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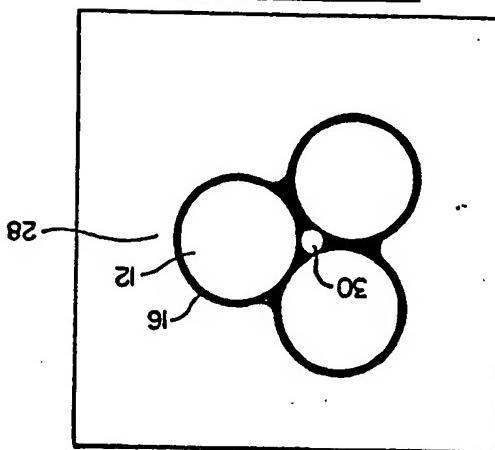


FIG-4

(5) The present invention provides a ceramic composite (28) having an open porous network and a controlled pore size comprising a plurality of ceramic particles (12) having a fused glass coating (16) and bonded to adjacent ceramic particles (12) at their interfaces by the glass coating (16). Pores (30) form in the ceramic material (28) produced by the same. The ceramic particles (12) are enveloped by and bonded to adjacent ceramic particles (12) producing the same. The ceramic particles (12) having a fused glass coating (16) and a method for producing a controlled pore size invenation provides a ceramic composite (28) having an open porous network and a controlled

(6) Controlled pore size ceramics particulary for orthopaedic and dental applications.

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The present invention relates to a ceramic having a controllable pore size, more particularly, to a controllable pore structure, liquid phase sintered ceramics for orthopaedic and dental applications.

Ceramic materials which are useful as bone substitutes are used in numerous orthopaedic and dental implants, and in some selected instances, orthopaedic implants have been approved for general dental

uses, the use of such materials in orthopaedic and dental clinics. However, these materials are only available in particulate or solid bulk closed cell forms.

Bone substitutes such as hydroxyapatite have been applied to other agents in various medical applications.

Surgical cements including hydroxyapatite as the bone substitute are used in numerous orthopaedic and dental applications including repairing bone fractures, and in filling or aligning comminuted fractures, and in filling or aligning cavities. Examples of such compositions are described in U.S. Patent Nos. 4,518,430 to Brown et al; and 4,542,167 to Aoki et al. U.S. Patent No. 4,451,235 to Okuda et al discloses a dental root material comprising hydroxyapatite and an organic matrix such as polyethylene.

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CONTROLED POR SIZE CERAMICS PARTICULARLY
FOR ORTHOPAEDIC AND DENTAL APPLICATIONS

U.S. Patent No. 4,135,935 to Fiegel et al discloses a composite material useful as an implant. A first starting material which is preferably a glass and a second starting material which is preferably a ground glass mixture having about 200-500 microns. The resultant mixture is finely comminuted to a particle size preferably between 20-50 microns. The mixture is compacted to form shaped bodies and sintered. This material does not have the open porosity characteristic of ceramic materials having a glass coating which bonds the ceramic particles at their interfaces. While the present invention is particularly directed to providing a porous network of controlled pore size and surgical applications, those skilled in the art will appreciate that the teachings herein are relevant to ceramic compositions generally where a controlled pore size is desired.

By varying the size of the ceramic particles and the thickness of the glass coating, the pore size of the composite ceramic can be varied.

According to one aspect of the present invention, ceramic particles have a coating of a fused glass on the surface thereof.

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- Accordingly, one object of the present invention is to provide a ceramic material having a controlled pore size.
- A further object of the present invention is to provide a ceramic composite having a controlled pore size comprising a plurality of particles of a bone ingrowth promoting material useful in dental and orthopedic applications wherein size useful in dental and orthopedic applications wherein the degree of resorbability can be varied.
- An additional object of the present invention is to provide a ceramic composite having a controlled pore size to promote a plurality of particles of a bone ingrowth comprising a plurality of particles of a bone ingrowth.
- Another object of the present invention is to provide ceramic particles having a finely divided or fused glass coating useful in preparing a ceramic composite in accordance with the present invention.
- Still another object of the present invention is to provide a process for preparing a ceramic composite in to provide other objects and advantages of the present invention.
- Other objects and advantages of the present invention in ventilation will become apparent from the following description in which the apparatus of the present invention is described.
- In order that the invention may be more readily understood, reference will now be made to the accompanying drawings, in which:
- Figure 1 illustrates an agglomerator useful in coating the ceramic particles of the present invention
- Figure 2 illustrates a spray dryer useful in coating the ceramic particles of the present invention
- Coating the ceramic particles of the present invention
- With a ground glass.

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Figure 3 illustrates the ceramic particles of the present invention with a glass powder coating prior to sintering. Figure 4 illustrates a plurality of the ceramic particles of the present invention with a glass coating after liquid phase sintering.

Figure 5 is a scanning electron microscope photograph (magnification 50X) of a ceramic in accordance with the present invention showing the glass coated ceramic particles and the glass necking between them.

Figure 6 illustrates a prostheses carrying ceramic particles in accordance with the present invention.

As stated earlier, the principal object of the present invention is to provide a ceramic composite having a controlled pore size. In order to achieve this object, knowing the size of the ceramic particle and the thickness of the glass coating, the pore size of the ceramic material can be calculated by using the equation for closely packed particles. The ceramic particles used in the present invention typically have a particle size of less than about 2000 microns. If the particle size is larger than about 2000 microns. If the particle size is larger than 2000 microns, the present invention can be used, but usually there are more expedient means available to achieve about 2000 microns. The amount of glass necking is also less and the porous ceramic is not as strong. Preferably, the ceramic particles of the present invention have a size of about 100 to 1000 microns and, more preferably, a size of about 100 to 1000 microns.

The ceramic composite of the present invention has broad application because the ceramic particles can easily be applied to 1000 microns.

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be any of a variety of ceramic materials. It is useful in providing bone implants, surgical cement or grafts, and drug delivery devices. Outside of the biomaterial field its open cell pore structure is useful in providing

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10 In making the ceramic material of the present invention, the glass is ground to a particle size of about 10 to 50 microns and coated on the surface of about 15 particles as a slurry in a solution of a binder such as polyvinyl alcohol (PVA). When the ceramic is subsequently sintered, the binder burns off. The coating is typically about the thickness of the glass particles as a result of the weight ratio of the ceramic coatings may also be useful. The weight ratio of the ceramic particles to the glass coating is about 8:1 to 14:1 and preferably about 10:1 to 12:1. In a preferred embodiment, the ratio which provides a desirable thin coating with good porosity and good necking between the ceramic particles is about 11:1. Of course, this will vary with the particle size of the ceramic.

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	Example	CaO	P ₂ O ₅	Na ₂ O	K ₂ O	Al ₂ O ₃	MgO	ZnO	SiO ₂
5	A	10	--	12	--	1	3	--	74
B	--	58	--	37	5	--	--	--	
C	--	56	--	21	20	--	3.0	--	
D	--	63	--	30	7	--	--	--	
E	20	80	--	--	--	--	--	--	

TABLE I

In order of increasing resorbability:

In Table I below, glass compositions are provided

Methods for obtaining hydroxyapatite and tricalcium phosphate particles can also be used. One is sol-gel processing, a method of preparing solid materials that result when certain combinations of chemicals are mixed and precipitated from solution. The second is a process that provides to high density. Can yield very fine grained ceramic sinters slowly, and particles of well controlled size and shape by using spray drying and agglomeration techniques which, until now, were used primarily in the food and drug industry. A slurry of dry ing and agglomeration techniques which, until now, were Enginering, Inc. Somevillle, N.J.) where it is atomized into fine droplets which are rapidly dried to yield relatively uniform spheres of the ceramic which are relatively inerting for example in a tunnel kiln. Both techniques after sintering provide dense, spherical shaped ceramic particles such as hydroxyapatite or tricalcium phosphate in controlled sizes which may be used to form the porous ceramic of the invention. These materials are also available commercially.

Figure 1 illustrates an agglomerator 10 useful in coating the ceramic particles of the present invention

with glass. Ceramic particles 12 are fed by air through tube 14 into the agglomerator 10. A slurry of a glass powder 16 in a binder is fed to a rotary disc 18 through tube 17. As the disc 18 rotates, the glass powder 16 collides with and coats ceramic particles 12. The glass coated particles roll off the plate 18 and are dried in tube 17.

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5 TCP, when formed by spray drying or agglomeration, are sintered prior to coating with glass. This sintering is usually performed by the manufacturer of commercially available materials. However, a continuous process is envisaged in which the sintered particles are fluidized and contacted with the glass powder while they are at an elevated temperature such that the glass films out directly on contact with the surface of the particle.

10 To promote bone ingrowth, the ceramic material of the present invention should have, or acquire through resorption, a pore size of at least about 100 microns. Incubating other applications, the ceramic material has a factor in controlling the rate of resorbability of the ceramic particle composition, the glass thickness is a fastener resorbable ceramic composite.

15 In addition to the glass composition and the fastener resorbable ceramic composite, the glass coating is thicker than for a ceramic composite. In general, for a slowly resorbable ceramic composite, the glass coating is thicker than for a typical soda lime glass).

20 If one then wanted to increase the resorbability of the complete nonresorbable ceramic composite, hydroxyapatite particles can be coated with an insoluble glass such as Example 1 (a

25 example of a completely nonresorbable ceramic composite, hydroxyapatite particles can be coated with an insoluble glass such as Example A in Table I (a

30 tricalcium phosphate ceramic particle coated with a glass comprising CaO and P₂O₅ in a weight ratio of about 20:80. Thus, the ceramic composites of the present

invention have broad applicat ion because the degree and rate of resorption can be widely varied by carefully choosing the proper combination of ceramic particl e composition, glass composition and its thickness.

When selecting a ceramic composite and glass for use in the ceramic composite, the mechanical strength of the implant and the rate of bone ingrowth should be considered. The ceramic having a small pore size exhibits a high strength but a lower rate of ingrowth compared to a ceramic having a larger pore size. If the ceramic and/or glass is resorbable, the pore size will increase as the ceramic ages.

In particular, it is anticipated that a ceramic will be designed to have high strength initially until a callus has formed around the implant and become fully mineralized. By carefully designing the resorption rate of the glass and/or the ceramic particle, the resorption rate thus, the resorption rate of the new bone has enough strength. Only be absorbed after the new bone has enough strength.

Less than the rate at which new bone forms, the resorption rate of the ceramic typically will be cut to the desired size by the practitioner. In another application, ceramic particles coated with glass powder or fused glass powder are sold to the surgeon who would have his own furnace and mold. The mold is filled with the fused glass powder to the desired shape is inserted.

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In another application, it is anticipated that the glass coated ceramic particles could be adhered to the surface of a prosthetic device to enhance bone attachment to the device. This is accomplished by first applying a surface of a prosthetic device to the glass coated ceramic particles and then sintering. Figure 6 shows thin glass coating to the prostheses, adhering glass coated particles to the prostheses and then sintering. It is an example of a prosthesis 40 used in hip replacements. The shank 42 of the prosthesis is driven into the bone, by applying glass-coated ceramic particles 44 to the shank, bone growth around the prosthesis and attachment of bone to the prosthesis is promoted.

The present invention is illustrated in more detail by the following non-limiting examples:

Example 1

hydroxypatite (HA 500, a product of Orthomatrix, Inc.) approximately 2 g of a spherical particulate was screened to 40 x 60 mesh was placed in a glass dish, 4 to 5 drops of a saturated solution of polyvinyl alcohol was added to the HA. The HA was coated with the PVA solution by spreading it through the solution with a spatula until it is well coated (approximately 3 to 5 minutes). The PVA coated HA was dried at 90°C and separated with a spatula. Glass composition E (Table I) was ground to 10-40 microns and sprinkled over the PVA coated HA. The mixture was then vibrated to uniformly coat the HA particles (approximately 1-2 minutes). The glass composition uniformly 30 place the plunger of the die approximately 3/8 inch. 100 hydraulics press. Enough HA was placed in the die to disperse particles were placed in a 7/32 inch die on a cliftion adhered to the HA particle surfaces. The glass coated HA was vibrated for 1-2 minutes. The glass composition uniformly 25 then vibrated to uniformly coat the HA particles (approximately 1-2 minutes).

then sprayed over the PVA coated HA. The mixture was and sprayed over the PVA coated HA. The mixture was then vibrated to uniformly coat the HA particles (approximately 1-2 minutes).

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The procedure was evenly coated with a thick
slurry of a glass having composition E in Table I using a
paint brush. The slurry on the surface of the prostheses
was dried at 90°C and glazed by heating at 1000°C for 5
minutes. Glass coated hydroxyapatite particles were pre-
pared as in Example 1 above and spread on the prostheses
and dried. The prostheses was then fired at 1000°C for 5
minutes and allowed to cool slowly.

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Having described the invention in detail and by
reference to preferred embodiments thereof, it will be
apparent that modifications and variations are possible
without departing from the scope of the invention as
defined in the appended claims.

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Hydroxyapatite was bonded to a prostheses using
the following procedure:

Example 2

The PVA solution running out of the die (30-60
seconds). The press was activated and the HA particles
were compacted (approximately 500 psi). The compacted
cylinder was removed from the die and dried at 90°C for
approximately 4 hours. The dried cylinder was sintered at
1000°C for 5 minutes.

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And the plunger was replaced and the die vibrated until
the PVA solution stopped running out of the die (30-60
seconds). The press was activated and the HA particles
were compacted (approximately 500 psi). The compacted
cylinder was removed from the die and dried at 90°C for
approximately 4 hours. The dried cylinder was sintered at
1000°C for 5 minutes.

1. A ceramic composite (28) having an open porous network of a controlled pore size comprising a plurality of ceramic particles (12) having bonded to their surfaces, said ceramic particles (12) a coating of a fused glass (16) on their surfaces, said ceramic particles (12) being bounded to adjacent ceramic particles (12) at their interfaces by said fused glass (16) to provide an open porous network between said ceramic particles (12).
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2. A ceramic composite (28) according to claim 1, characterized in that said ceramic particles (12) are a material selected from the group consisting of Al_2O_3 , MgO , ZrO_2 , and SiC .
3. A ceramic composite (28) according to claim 1,
characterized in that said ceramic composite (28) is useful for dental and orthopaedic implants and said ceramic particles (12) are a bone ingrowth promoting
4.
4. A ceramic composite (28) according to claim 3,
characterized in that said ceramic particles (12) are a nonresorbable bone ingrowth promoting material.
5. A ceramic composite (28) according to claim 4,
characterized in that said nonresorbable bone ingrowth promoting material is selected from the group consisting of hydroxyapatite, alumina oxide, and pyrolytic carbon.

CLAIMS

6. A ceramic composite (28) according to claim 3, characterized in that said ceramic particles (12) are a resorbable bone ingrowth promoting material.
7. A ceramic composite (28) according to claim 6, characterized in that said ceramic material is selected from the group consisting of calcium aluminate, calcium phosphates, calcium aluminophosphates and calcium sulfates.
8. A ceramic composite (28) according to claim 7, characterized in that said ceramic composite (28) has a pore size of about 20 to 150 microns.
9. A ceramic composite (28) according to claim 8, characterized in that said ceramic composite (28) has a pore size of at least about 100 microns.
10. A ceramic composite (28) according to claim 9, characterized in that said glass (16) is resorbable.
11. A ceramic composite (28) according to claim 10, characterized in that said said glass (16) is resorbable glass comprising calcium oxide (CaO) and phosphorus pentoxide (P₂O₅).

12. A ceramic composite (28) according to claim 11, characterized in that said resorbable glass comprises by weight:
- | | | | | | | | | | |
|-----|-------|-------------------------------|--------|------------------|------|------------------|------|----|-------|
| CaO | 5-50% | P ₂ O ₅ | 50-95% | CaF ₂ | 0-5% | H ₂ O | 0-5% | XO | 0-10% |
|-----|-------|-------------------------------|--------|------------------|------|------------------|------|----|-------|
- wherein XO is a metal oxide selected from the group consisting of magnesium, zinc, strontium, sodium, potassium, lithium and aluminum oxides.
- 10
13. A ceramic composite (28) according to claim 12, characterized in that said ceramic particles (12) have a particle size of less than about 2000 microns.
14. A ceramic composite (28) according to claim 13, characterized in that said ceramic particles (12) have a particle size of about 500 to 1000 microns.
15. A ceramic composite (28) according to claim 14, characterized in that the ratio of said ceramic particles (12) to said glass coating (16) based on the weight of said ceramic composite (28) is about 8:1 to 14:1.

16. A ceramic composite (28) according to claim 15, characterized in that said ceramic composite (28) is formed by coating said ceramic particles with fusible glass particles (16), molten said fusible glass particles coated glass particles (16), molting said glass particles (20) into a desired shape and sintering.
17. A ceramic composite (28) according to claim 16, characterized in that said ceramic composite (28) is coated with said fusible glass particles (16) in an agglomerator (10) or a spray dryer (22).
18. Ceramic particles (12) having a coating of a fused glass (16) on the surface thereof.
19. Ceramic particles (12) according to claim 18, characterized in that said ceramic particles (12) are coated with said fusible glass particles (16) according to claim 19.
20. Ceramic particles (12) according to claim 19, characterized in that said ceramic particles (12) are bone ingrowth promoting material.
21. A process for preparing a ceramic composite (28) having a controlled pore size comprising the steps of: having a ceramic particulate (12) with a glass (16), casting ceramic particles (12) with a glass (16), molding said glass coated ceramic particles (20) into a desired shape, and

22. A process according to claim 21, characterized in that said glass (16) is a fusible glass powder.
23. A process according to claim 22, characterized in that said ceramic particles (12) are coated with said spray dryer (22).
24. A ceramic composite (28) according to claim 9, characterized in that said glass (16) is non-tresorable.

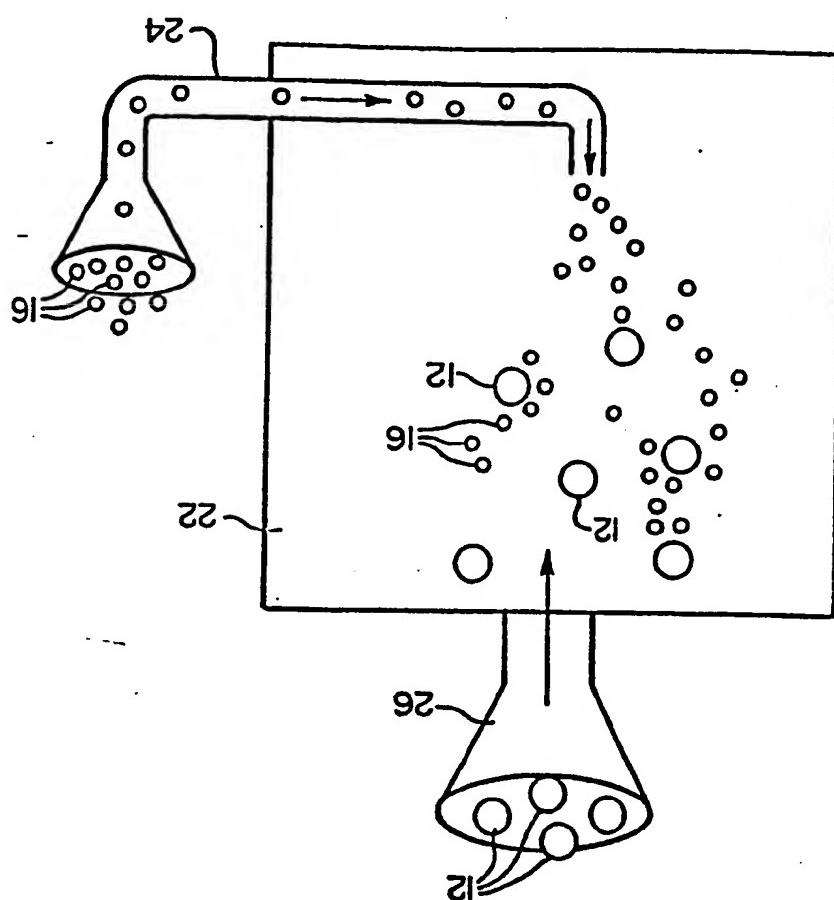


FIG-2

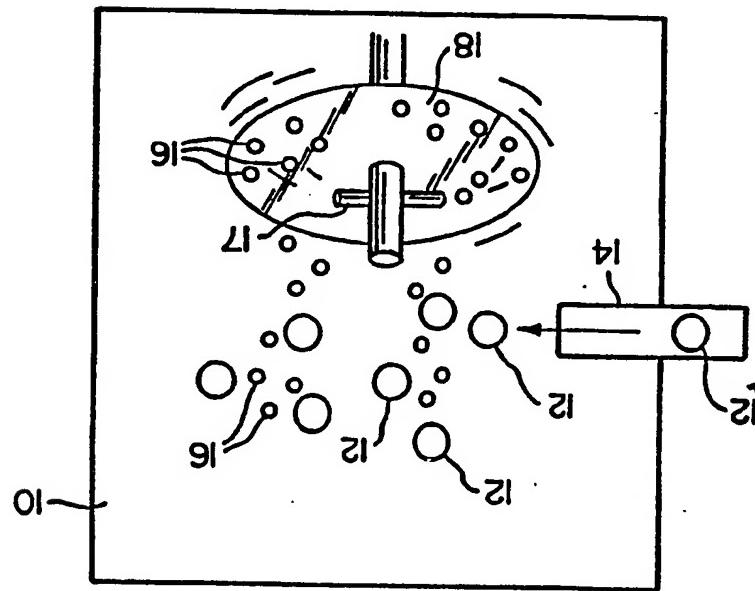
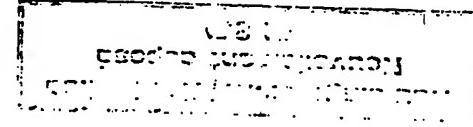


FIG-1



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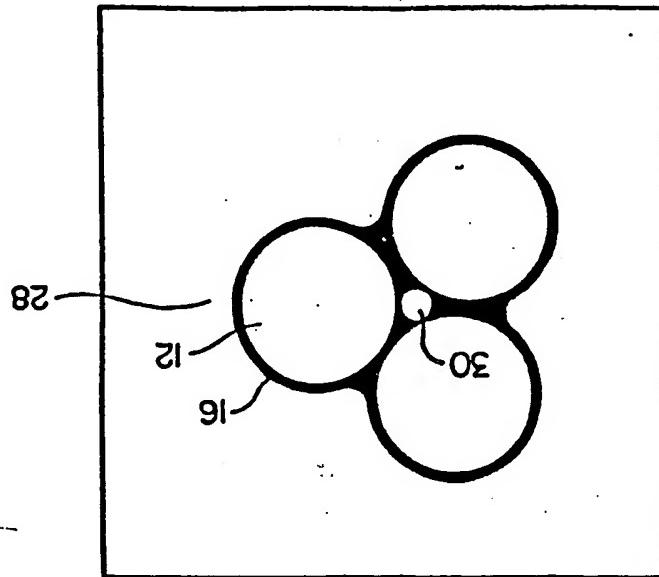


FIG-4

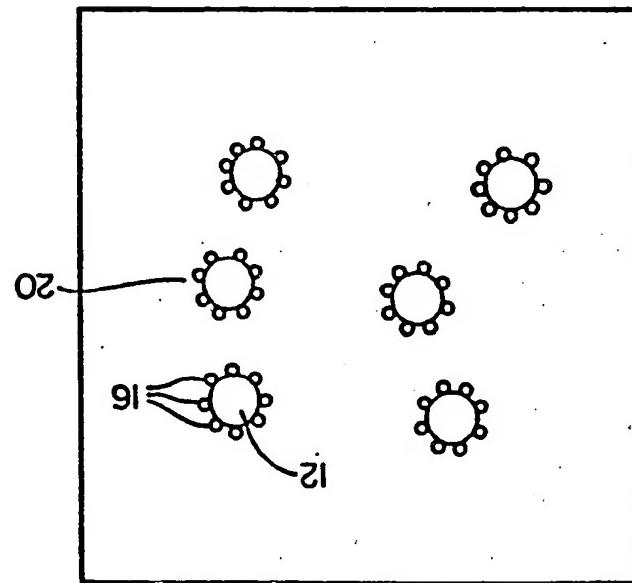


FIG-3

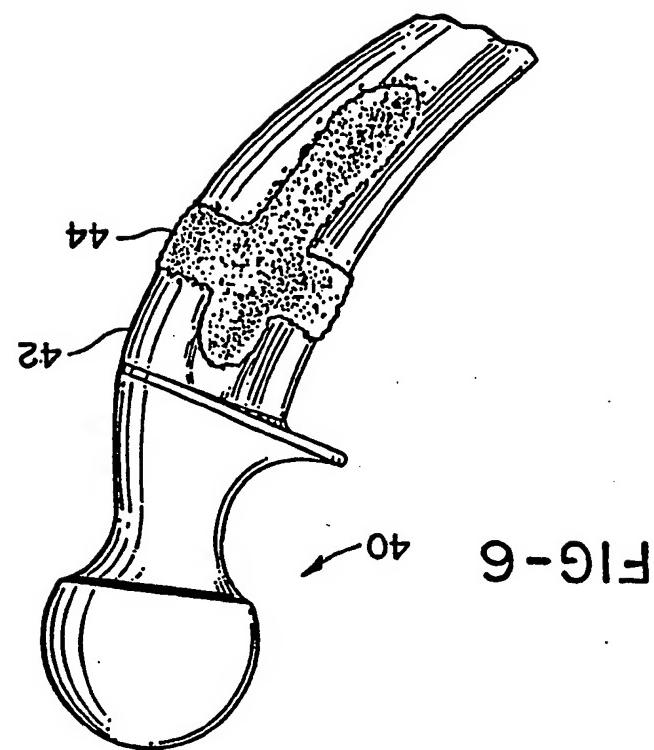


FIG-6

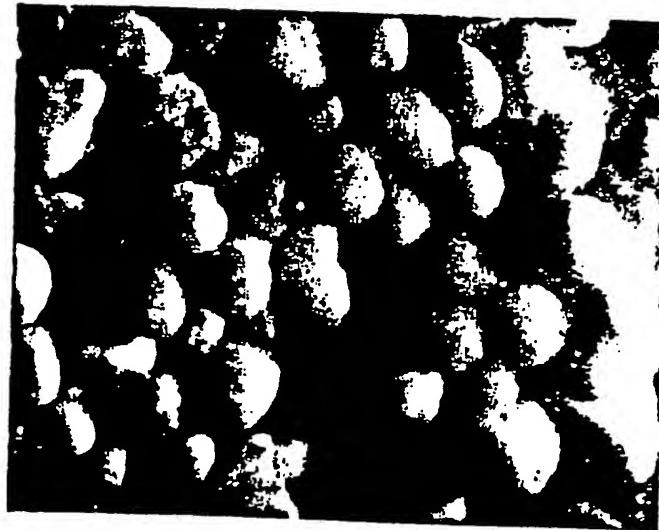


FIG-5

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICANT (Int. Cl. 4)
Y	* Claim 1 * US-A-4 156 943 (J.P. COLLIER)	18, 8, 9,	---
Y	* Claim 1; US-A-1 929 425 (E.T. HERMANN)	18 1, 8, 9, ---	2, Times 24-30 * * Claim 1; page 1, Times 92-102; page A 61 F 2/30 A 61 K 6/06 C 03 C 4/00 C 04 B 38/00
A	WO-A-8 604 807 (UNIVERSITY OF DAYTON)	1, 10-12	* Abstract * ---
A	US-A-4 475 892 (F.R. FUNCE)	1	* Figure 9; Column 10, Times 34-38; Claims 1, 14, 15 * ---
A	GB-A- 701 802 (R.W. YOUNG)		---
A	DE-A-3 445 711 (K. DRAENERT)		---
The present search report has been drawn up for all claims			
TECHNICAL FIELDS SEARCHED (Int. Cl. 4)			
A 61 K 6/00 A 61 L 27/00 A 61 F 2/00 C 03 C 4/00 C 04 B 38/00			
Place of search Date of completion of the search Examiner			
THE HAGUE 24-02-1988 DAELMAN P.C.A.			
CATEGORY OF CITED DOCUMENTS			
T : theory or principle underlying the invention E : either patent document, but possibly the invention X : particularly relevant if taken alone Y : document cited in the application Z : document cited for other reasons D : document cited in the application J : member of the same family, corresponding document O : non-written disclosure P : intermediate document			

EP 87 31 0161

 European Patent Office
 EUROPEAN SEARCH REPORT
 Application Number
